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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,316	03/17/2006	Robert Jongejan	27233U	8025
34375 7590 06/10/2011 NATH & ASSOCIATES PLLC 112 South West Street Alexandria, VA 22314			EXAMINER DEMILLE, DANTON D	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 06/10/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,316	Applicant(s) JONGEJAN ET AL.	
	Examiner DANTON DEMILLE	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 requires the sensor to be positioned externally to the drug delivery device mouthpiece. As noted in the last office action, the drug delivery device is not part of the claimed combination, so it is not clear how much weight can be given this limitation. In order to know whether or not the sensor is external to the drug delivery device one would have to have the drug delivery device present.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4, 8, 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US 5,284,133) in view of Sprinkel, Jr. (US 5,261,424).

Burns teaches a compliance monitor for a drug delivery device 10 comprising a switch 44, a "lip sensor arrangement includes a pair of spaced apart electrical contacts 76 at the mouth piece 14 which are connected to the controller 24 by wire 78. When the patient presses the contacts 76 together with his mouth during actuation, delivery of the drug to the patient is confirmed", column 12, lines 18-23. While the switch of Burns is a pressure switch, there appears to be no unobviousness to using other equivalent alternative switches that perform the same function. A conductivity switch or a light sensor or a temperature sensor would have been obvious equivalent alternative means for performing the same function. Sprinkel teaches the use of a lip sensor for monitoring when the lips are placed on the tip of a flavor generator which then

initiates heating of the flavor-generating material. Sprinkel teaches a piezoelectric sensor that can be used to detect the change in temperature that occurs when the flavor generator is placed between the user's lips, sentence spanning columns 2 and 3. It would have been obvious to one of ordinary skill in the art to modify Burns and use a temperature sensor as taught by Sprinkel as an obvious equivalent means for detecting lips being placed upon a mouthpiece. Moreover, since applicant's own invention teaches that the proper position sensor can either be a light sensor or a conductivity sensor or a temperature sensor proves that there is no criticality to any one type of sensor. Any conventional type of sensor to detect body positioning can be used.

Regarding claim 2, the sensor 76 is positioned externally to the drug delivery device 10 so that the sensor does not affect the normal operation of the drug delivery device.

Regarding claim 4, Burns teaches a timer 26 that acts as a clock.

Regarding claim 13, Burns teaches the change in an output of the sensor is characteristic of correct use of the drug delivery device, column 12, lines 18-31.

Regarding claims 14 and 15, Burns teaches an input/output device 32 for downloading the information stored therewithin, column 9, lines 36-39.

Regarding claim 16, docking stations are old and well known and would have been an obvious equivalent means for downloading or uploading information into the system.

Regarding claim 17, Burns teaches using a remote computer that would have computer-readable medium for carrying computer program for programming to receive and process data downloaded from the monitor.

Regarding claims 19-22, Burns teaches the method of using the compliance monitor as claimed.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4, 8 and 13-22 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that Burns does not teach or suggest that any of the timer, actuating means and signaling device can be removably attachable to the drug delivery device, much least the controller. Burns teaches the timer 26, actuating means 28 and signaling device 30 are part of the MDI. The MDI is separate and removably attachable to the drug delivery device 10.

Sprinkel is merely cited to teach an obvious equivalent sensor to the sensor 76 for detecting whether the device is properly positioned in contact with the user's body. Sprinkel is not cited to teach a compliance monitor that is removably attached to the drug delivery device. Sprinkel doesn't have to. Burn's already anticipates that limitation.

Therefore the prior art teaches every positive limitation claimed as required by *In re Wilson*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974.

The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7 June 2011

/Danton DeMille/
Danton DeMille
Primary Examiner
Art Unit 3771